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EXAMINER	
UNDERDAHL, THANE E	

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1651	

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09/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/570,835

Applicant(s)

ARZT ET AL.

Examiner

Thane Underdahl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to the Applicant's reply received 7/16/07. Claims 5-11 are pending. No claims are withdrawn. Claims 1-4 were cancelled. 5, 8, and 9 have been amended. Claim 11 is new.

#### **Response to Applicant's Arguments-Double Patenting**

The Applicant traverses the Nonstatutory Double Patenting Rejection on the grounds that Brasile does not teach a protective sack for receiving a transplant organ and that also serves as a reservoir for dialysate fluid. However these teachings by Brasile are identified below and the Provisional Double Patenting Rejection stands.

#### **Response to Applicant's Arguments— 35 U.S.C § 112**

In the response submitted by the Applicant, the 35 U.S.C § 112 2<sup>nd</sup> paragraph rejection of claims 5-10 over were considered but not found persuasive.

Claim 5 was deemed indefinite since it was unclear if the vitality-preserving fluid and the storage fluid were two distinct fluids or a mixture of the two fluids. As written the claim continues not to indicate the difference between the fluids. While the Applicant argues that the "vitality-preserving fluid comprises a dialysate circulation system and a perfusate circulation system and that the dialysate is a component of the dialysate circulation system" this does not clarify how the dialysate or the dialysate circulation system are integrated into the vitality-preserving fluid circuit.

However the indefiniteness of claims 8 and 9 have been clarified by Applicant's amendment but because claims 6-11 depend from indefinite claim 5 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Therefore the rejection stands and is repeated below.

Claims 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 refers to two fluids: a vitality-preserving fluid and a storage fluid. It is unclear if these are two distinct fluids, are a mixture of fluids or the same fluid since as the claim is written the storage and vitality-preserving fluids are kept in the same perfusion chamber and ran through the same dialysis circuit. Also claim 5 includes the phrase "wherein said vitality-preserving fluid includes a dialysate circuit" is indefinite since it is unclear if it is the fluid that is ran through a dialysis circuit or the fluid is a dialysate. Clarification is required.

#### New Rejections Necessitated by Amendment

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendments made to claim 5 compound its indefiniteness. The term and composition of the vitality-preserving fluid (VPF) is unclear. While the Applicant limits that the vitality-preserving fluid circuit is circulated in a VPF circuit that includes a dialysate and perfusate circulation system, it is unclear what products of the dialysate

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and perfusate circulation system are included (in any) in the VPF. The limitation of "storage fluid" is indefinite because while the Applicant teach that the storage fluid is a "dialysate" that is "a component of and integrated into said dialysate circulation system" it is unclear exactly how using the product of the dialysate circulation system (DCS) contribute to the storage fluid. It is unclear if the storage fluid is directly mixed with the dialysate circulation fluid in the system or is a component used to assist the DCS in performing its duties and is not directly mixed with the product of the DCS. Furthermore it is unclear if the dialysate that makes of the storage solution is the same dialysate found in the DCS. Also while the claim limits that the "vitality preserving fluid circuit" includes a "dialysate circulation system and a perfusate circulation system" it is unclear if the dialysate and perfusate of these systems are actually components of the VPF or mere support apparatus for cleaning the VPF. Clarification is required.

In the interest of compact prosecution, claim 5 will read as follows:

"A storage system for extracorporeal storage of an organ comprising:

an organ perfusion chamber for storing an extracorporeal organ;

a vitality-preserving fluid circuit for circulating a vitality-preserving fluid into said extracorporeal organ stored in said organ perfusion chamber, said vitality preserving fluid circuit comprises a dialysate circulation system and a perfusate circulation system that administers and recycles the vitality preserving liquid as it flows through the organ;

a storage fluid inside the organ perfusion chamber that serves as a reservoir for the vitality-preserving fluid that flows through the organ;

a protective sack that receives the extracorporeal organ and provides a barrier to the storage fluid;

wherein the protective sack that holds the extracorporeal organ is floating on the storage fluid in the organ perfusion chamber.”

### **Response to Applicant's Arguments— 35 U.S.C § 102**

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 5 and 6 over Brasile were considered but not found persuasive.

The Applicant argues that Brasile does not teach an organ storage chamber that does not enclose the organ. The Examiner found no limitation in claim 5 or 6 that required the organ be enclosed instead of being cradled. Furthermore the Applicant argues that Brasile does not teach that the organ storage chamber is “otherwise not filled with a fluid that supports the weight of the organ to hold in a floating state” (Applicant’s response, page 6, paragraph 5). However the Applicant’s attention is drawn to paragraph 67 of Brasile which teach “Organ support member 36 may be made of...a mesh-like fabric which suspends the organ in a sling-like fashion” and that the support member is a “pouch or sac, capable of conforming to the shape of an organ which is placed on it” (paragraph 67). Looking at Figure 2 the organ support member is hanging the organ above an effluent reservoir (38), which is a liquid (paragraph 62). Therefore this design inherently suspends the organ with a flexible sack that conforms to the shape of the organ and that floats on the liquid reservoir beneath it. The effluent passes through a 0.22 micron filter on its way to the dialysis (paragraph 78).

Therefore the rejection stands and is repeated below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 6 remain and new claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Brasile (U.S. Patent Application Publication # 2002/0012988).

These claims are drawn to a system for extracorporeal storage of organs.

The system further comprises a temperature control device in the organ perfusion chamber to control the temperature of the storage fluid.

Brasile teach a system for the extracorporeal storage of organs that includes a perfusion chamber and a dialysis machine that circulates and purifies the vitality preserving storage liquid (Fig 1 and paragraph 23). The organ is held in a pouch or sack made of impermeable plastic such as silicon (paragraph 67). The chamber includes a reservoir that replenishes the fluid circuit as it flows over the organ and is purified. The system includes a temperature control device to control the temperature of the vitality preserving storage fluid inside the perfusion chamber (page 2 paragraph 12).

Therefore the reference anticipates claims 5 and 6.

#### **Response to Applicant's Arguments— 35 U.S.C § 103**

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 5-9 over Brasile and claims 5, 6, 8-10 over Brasile in view of Bacchi et al. were considered but not found persuasive.

In both instances the Applicant argues that since claim 5 is allowable then the dependant claims are allowable. However as detailed above claim 5 remains rejected and in the absence of evidence to the contrary so too do the dependent claims.

Therefore the rejections stand and are repeated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 8, and 9 remain and new claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5 and 6 in the above rejection.

The description and rejection of claims 5, 6 and 10 are listed in the 35 U.S.C § 102(b) rejection above.

Claim 8 limits the temperature control device is integrated into the wall of the organ perfusion chamber. Claim 9 limits that the temperature control device comprises temperature control loops embedded in the organ perfusion chamber.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). However Brasile does not specifically teach a temperature control device integrated into the wall of the organ perfusion chamber. However based on the disclosure by Brasile it would be prima facie obvious at the time of filing to modify the



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invention to integrate the temperature control device into the wall, since Brasile already places the temperature control sensors of the device in the perfusion chamber.

Furthermore M.P.E.P. § 2144.04 B state that making a device integral "would be merely a matter of obvious engineering choice" and as such is *prima facie* obvious to make the temperature control device integral with the perfusion chamber.

Also since Brasile teach that the temperature controller maintains the temperature between 25-37 °C based on the input it receives from the sensor (page 7, paragraph 60) it is obvious that one of ordinary skill in the art would recognize that the system contains temperature control feedback loops.

Claim 7 limits the temperature control device to a heating mat.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). Brasile does not teach that the heat exchanger is a heating mat. However it would have been obvious to someone skilled in the art at the time the invention was made that multiple methods can be used to heat the storage solution included a water heater to circulate warmed water around the reservoir (page 7, paragraph 60). One of ordinary skill in the art would recognize that a heat exchanger can include heating elements as well as a heating mat since both are known in the art to heat liquid as taught by Cooksley et al. (col 2, lines 65-70). Therefore it would be *prima facie* obvious to use a heating mat as a heat exchanger for the perfusion chamber. The reference above render obvious claims 5-9.

Claims 5,6, and 8-10 are and new claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile as applied to claims 5, 6, 8, and 9 above, and further in view of Bacchi et al. (U. S. Patent # 5,285,657, 1994).

The description and rejection of claims 5, 6, 8, and 9 and new claim 11 are listed in the 35 U.S.C § 103(a) rejection above by Brasile et al. Claim 10 further limits that the organ perfusion chamber is hermetically sealed against fluid and pressure.

While Brasile does teach an organ perfusion chamber in combination with a temperature control device and dialysis system he does not specifically teach that the organ perfusion chamber is hermetically sealed against fluid and pressure. He does teach that it is important to minimize perfusion contamination due to contact with air (Brasile, page 9 paragraph 78) which provides motivation to hermetically (airtight) seal the chamber. However it would have been obvious to someone skilled in the art at the time the invention was made to make the organ perfusion chamber hermitically sealed in view of Bacchi et al. who teach an insulated organ perfusion chamber (Bacchi, col 1, lines 45-50) for extracorporeal organ transport (Bacchi, see abstract). Bacchi et al. teach that the lid of this chamber is hermetically sealed (col 7, line 45-50).

It would have been obvious to someone skilled in the art to modify the invention of Brasile with the hermetically sealed lid taught by Bacchi et al. The motivation is provided by Brasile who desires minimal contact with air and the organ. Bacchi et al. provides the reasonable expectation of success by making an organ perfusion chamber that is hermetically sealed.

Furthermore, M.P.E.P. § 2144.06 holds that it is obvious that since both devices are known for the same purpose (extracorporeal organ storage) it would be obvious to combine the elements of both devices to form a their device used for the same purpose.

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 5,6, and 8-10 are not allowable.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims**

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(MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

#### CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

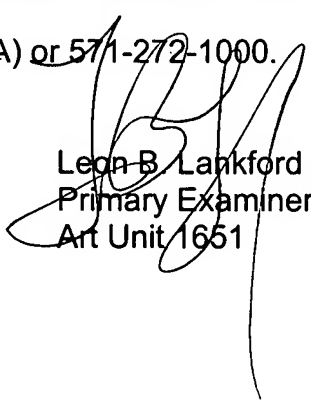
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Art Unit 1651



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